

CLAIMS

1. Heat-sensitive composition in liquid form, containing
 - 5 - a hydrophobic organic liquid,
 - an organogelling substance, the molecules of which have the capacity to bind together via bonds of low energy, and
 - 10 - a bioactive substance,which changes to the organogel form when it comes into contact with a physiological fluid, during its administration to an animal body, in particular man.
- 15 2. Composition according to Claim 1, characterized in that the organogel is formed by cooling the site of application of the said composition.
- 20 3. Composition according to Claim 1 or 2, characterized in that it also contains a hydrophilic organic solvent capable of creating weak bonds with the organogelling substance, and that the organogel forms by diffusion of the said hydrophilic organic solvent into the aqueous
25 medium.
- 30 4. Composition according to Claim 1 or 2, characterized in that the said organogel has a transition temperature from the liquid state to the gel state which is lower than the temperature of the site of application when the organogel is administered without a hydrophilic organic solvent, and a transition temperature from the gel
35 state to the liquid state that is higher than the body temperature.
5. Composition according to Claim 4, characterized in that the said organogel has a transition

temperature from the liquid state to the gel state of less than 30°C and a transition temperature from the gel state to the liquid state of greater than +35°C.

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6. Composition according to one of Claims 3 to 5, characterized in that the proportion of the hydrophilic organic solvent is less than 60% and preferably less than 20% by weight of the said composition.
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7. Composition according to one of Claims 3 to 6, characterized in that the said hydrophilic organic solvent belongs to the group comprising ethanol, glycerol, benzyl alcohol, propylene glycol, 15 N-methylpyrrolidone and dimethyl sulphoxide (DMSO), poly(ethylene) glycol of low molecular weight, chlorobutanol, furfural, N,N-dimethyl-acetamide, glycerol formal, isopropylidene-glycerol, ethyl lactate, acetic acid and lactic acid.
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8. Composition according to Claim 7, characterized in that the said hydrophilic organic solvent is ethanol.
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9. Composition according to one of the preceding claims, characterized in that the said hydrophobic organic liquid belongs to the group comprising plant oils, triglycerides, semi-synthetic oils and water-immiscible organic solvents.
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10. Composition according to Claim 9, characterized in that the said hydrophobic organic liquid comprises soybean oil, squalene, benzyl benzoate, a 35 triglyceride or a mixture of benzyl benzoate and benzyl alcohol.

11. Composition according to Claim 9 or 10, characterized in that the said hydrophobic organic liquid is a mixture of different hydrophobic organic solvents.
12. Composition according to Claim 11, characterized in that the said mixture is a mixture of soybean oil and ethyl oleate.
13. Composition according to one of the preceding claims, characterized in that the said biologically active substance belongs to the group comprising proteins, peptides, amino acids, vitamins, nucleic acids and oligonucleotides.
14. Composition according to Claim 13, characterized in that the said biologically active substance is chosen from morphine, α -interferon, β -interferon, somatostatin, heparin, interleukins, erythropoietin, calcitonin, human growth hormone, thyreotrope hormone and leuprolide.
15. Composition according to one of the preceding claims, characterized in that the organogelling substance represents between 0.5% and 50% by weight relative to the total weight of the said composition.
16. Composition according to one of the preceding claims, characterized in that the organogelling substance is a molecule of low molecular weight with acid, alcohol or amine end groups, especially an amino acid derivative.
17. Composition according to Claim 16, characterized in that the organogelling substance belongs to the group of alanine ester derivatives.

18. Composition according to Claim 17, characterized in that the said organogelling substance is N-lauroyl-L-alanine methyl ester or N-lauroyl-L-alanine ethyl ester.
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19. Composition according to Claim 17, characterized in that the said organogelling substance is N-stearoyl L-alanine methyl ester or N-stearoyl L-alanine ethyl ester.
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20. Organogel obtained from the composition according to one of Claims 1 to 18, characterized in that it remains in stable gelled form between the temperature of application and the gel/liquid transition temperature of the said composition.
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21. Use of a composition according to one of Claims 1 to 20, for the manufacture of a medicinal product intended to be injected into the body via the extravascular parenteral route and especially subcutaneously, intradermally, intraperitoneally or intramuscularly, or intended to be administered intraocularly or vaginally, to an open wound or during surgery.
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22. Use of a composition according to one of Claims 1 to 20, for the manufacture of a medicinal product intended to be used as a vector for the sustained release of bioactive substance(s) into the body.
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21. Process for preparing a composition according to Claim 1, characterized in that the bioactive substance, optionally in aqueous solution, is added to the mixture consisting of the organogelling substance and the hydrophobic organic liquid.
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22. Process for preparing a composition according to
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Claim 3, which consists in

- dissolving the organogelling substance in the hydrophilic organic solvent, and then in incorporating the bioactive substance and the hydrophobic organic liquid.

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23. Process according to Claim 22, characterized in that when the bioactive substance is sparingly soluble or insoluble in the organic phase, an aqueous solution of the said substance is dispersed with stirring into the organic phase consisting of the organogelling substance and the hydrophilic organic solvent.

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